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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul J. Gilligan

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12/18/2002

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EXAMINER

FORD, JOHN M

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 12/18/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. <u>09/990131</u>	Applicant(s) <u>William J. Ford</u>
Examiner <u>J. M. Ford</u>	Group Art Unit <u>1624</u>

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 0430, 2002
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 2, 4 - P and 13 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 2, 4 - P and 13 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☒ Other Exhibit A

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Applicants' response of Oct. 30, 2002, is noted.

The claims in the applicant in are claims 1, 2, 4—8 and 13.

The heterocyclic expression in claim 1 in regard to



Forming a heterocyclic ring cannot be allowed. See the remarks below.

M on page 4 of the amendment contain<sup>ing</sup> claim 1 refers to aryl, and heter<sup>a</sup>aryl, alone, or in a combined term with other radicals. These expressions are not allowable, as noted further below.

$R^{21}$  is defined on page 5 as aryl where aryl is phenyl and naphthalene. Aryl is usually not considered to be indanyl or indenyl. Note the double bond difference. Aryl implies the radical is aromatic. Note In re Sus, 134 USPQ 301. There are multiple different definitions for aryl,  $R^2K$  cannot be a saturated heteroaryl. If it is saturated it is not aryl.

Are the aryl and heteroaryl of page 7 intended to apply to the entire claim?

Claim 1 is rejected under 35 USC 112, 2<sup>nd</sup> paragraph. Clarification is requested.

Heteroaryl is entirely inadequate. Where are the heteroatoms in the ring? How many hetero atoms are present in the ring. Applicants are placing specific conception with the reader. Not a fair burden in return for applicants getting a 17/20 year monopoly on compounds, not yet made. Adjacent O/S; O/O or S/S combinations have not been made, as they are notoriously unstable. What is the source of the starting materials? These are compound claims that carry with it the right to exclude others. Applicants should not be permitted to pre-empt others from future endeavors, when they, the

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public, finally do make the compounds included in the huge language applicants suggest.

Claim 1. is, therefore, also rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph, as the specification does not contain adequate representative exemplification for the breadth claimed. Even any and all combinations of the 1 to 3 hetero atoms, are not shown to exist.

The USPTO only recognizes: C, N, O, S, Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl.

Heterocyclic is not just a substituent; it is whole body of art, larger than the nucleus claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

What the heteroaryl is, may often control the classification and search of the molecule.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

What is intended by applicant, <sup>need be</sup> supported in the specification with sufficient representative exemplification. Note United Carbon Cp. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be

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capable of accurate definition, and it must be accurately defined to be patentable",  
above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic ~~reasons~~ for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

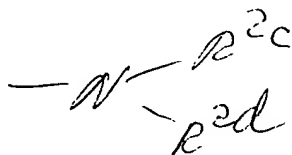
The written description is considered inadequate here in the specification. Conception should not be the role <sup>of</sup> the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 12, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

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Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Specific conception of what the intended heteroaryl ring, may be, should not be left to the reader. In regard to



One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring,.

What are the hetero atoms? What size is the *ring?*

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

It becomes necessary for applicants to indicate in the claims what they mean by heteroaryl. Heteroaryl, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purpose, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming and support in the specification for the variables sought.

This rests specific conception with the reader.

What exactly is intended, and where is that supported in the specification. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicant's breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they demonstrated as a specific fact.

The heteroaryl expression in claim 1 et seq., is not acceptable, as it does not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, *United Carbon Co. Vs. Binney & Smith Co.*, 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of claims held to this standard in *Lockhead Aircraft Corp. Vs. United States*, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have



limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

In regard to "aryl, note.

In re Sus, 134 USPQ 301, indicates that there are multiple different definitions of aryl. Note the footnotes in the In re Sus, above. Therefore, it becomes necessary for applicants to indicate what they mean by aryl. Similarly, heterocyclic has different definitions, as noted above, and requires clarification by applicants as to what they intend it to mean.

Note the Proviso at the end of claim 1. Closely related compounds would be obvious from the compounds removed by exception; In re Nomiya et al., 184 U.S.P.Q. 607. Applicants claim the next adjacent compound to the one removed. This type of close claiming cannot be allowed.

Page 9 of the amendment of 10-30-02 which contains a entire page of proviso removed compounds includes next adjacent compounds still claimed in the genus , Consider (a) ortho-hydroxy phenyl. What about the position isomers of *para* or *meta*, or methoxy rather than hydroxyl. Phenyl substitution and R<sup>1</sup> being -OCH<sub>3</sub> are all obvious variations, still claimed.

The entire page of (b) – (k) has easy next adjacent compounds still claimed ; methyl vs. ethyl; hydrogen vs. *methy*/different *halogen variations*.

These are prima facie obvious compounds from the compounds removed. See the last office action, Claim 1 is rejected under 35 U.S.C. 103.

Claim 2 is rejected, for the reasons claim 1 was rejected. See page 11, L is aryl and heteroaryl. Likewise M.



form a ring of unknown size. Each combination of  $O$ , N and S is a different patentably distinct ring with separate classification and search. These are rings claimed by applicant, but not shown to exist.

Claims 4, 5, 6, 8 and 13 are rejected as being dependent on a rejected claim.

Claim 7 is rejected for the reasons claims 1 and 2 as rejected. See  $R^5$  aryl, eteroaryl and heterocyclyl, p. 115 of spec. also, end of p. 115.

The next adjacent compound would be structurally obvious. See, *In re Dillon*, 919 F.2d at 696, 16 U.S.P.Q.2d at 1904. See also *Deuel*, 51 F.3d at 1558, 34 U.S.P.Q.2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compounds. For example, one compound may suggest its homologs, because homologs often have similar properties, and, therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

Other structural similarities have been found to support a prima facie case of obviousness. E.g., In re May, 574 F.2d 1082, 1093-95, 197 U.S.P.Q. 601, 610-11 (CCPA 1978) (stereo isomers); In re Wilder, 563 F.2d 457, 563 F.2d 457, 460, 195 U.S.P.Q. 426, 429 (CCPA 197) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 U.S.P.Q. 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 U.S.P.Q. 38, 41 (CCPA 1963) (omission of methyl group from pyrazole ring).

A compound need not be a homology or isomer of a prior art compound in order to be susceptible to a rejection based on structural obviousness.

Thus, a difluorinated compound was held unpatentable over the prior art di chloro compound on the basis of analogical reasoning. Ex parte Wiseman (POBA 1953) 98 U.S.P.Q. 277.

In re Nomiya, 184 USPQ 607, provides that it is reasonable to conclude that the compounds removed by exception are known.

We reject on compounds, not citations. It is, therefore, reasonable to reject the presently claimed compounds as obvious (35 U.S.C. 103) from the compounds removed by exception, whether we know the citation of the compounds or not.

Therefore, claim 1 is rejected as obvious (35 U.S.C. 103) from the compounds removed by exception.

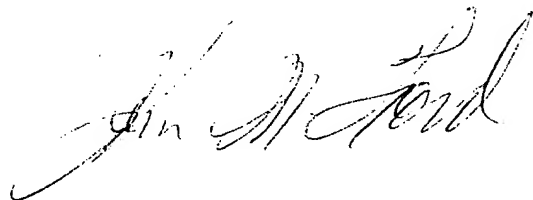
See the enclosed CAS on-line ~~print out~~ as Exhibit A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Ford whose telephone number is (703) 308-4721. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Ford/LR  
December 13, 2002



JOHN M. FORD  
PRIMARY EXAMINER

